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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,863	07/21/2003	Rogers C. Ritter	5236-000438	6412
28997	7590	12/15/2006	EXAMINER	
HARNESS, DICKEY, & PIERCE, P.L.C			EBRAHIM, NABILA G	
7700 BONHOMME, STE 400			ART UNIT	
ST. LOUIS, MO 63105			PAPER NUMBER	
			1618	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,863

Applicant(s)

RITTER ET AL.

Examiner

Nabila G. Ebrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 36-40 is/are pending in the application.
- 4a) Of the above claim(s) 25-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of the claim amendments and the Applicant remarks dated 10/4/06 is acknowledged.

Status of Claims:

Claims 1-23, and 36-40 are pending in the application.

Claim 24 was cancelled.

Claim 40 is new.

Rejections:

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. In light of claim 1 amendment the rejection of claims 1-5, 8, and 18-21 under 35 U.S.C. 102(b) as being anticipated by Ranney US 5213788 (Ranney) is hereby withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1-24, 36-39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ranney US 5213788 in view of Garibaldi et al. US 6364823 (Garibaldi), and further of view of Unger et al. US 6231834 (Unger).

Ranney discloses compositions and methods for selective access to tumor regions. This capability provides powerful contrast-enhancement agents for nuclear magnetic resonance imaging. A polyatomic complex, which includes intramolecular ferromagnetic coupling between metal atoms in the form of microspheres, which is associated with a polymer (abstract). Migration of particles and molecular aggregates (larger than 2 nm in diameter) can be accelerated by the application of appropriate surface coatings (col. 10, lines 49+). The preferred mean diameter falling between about 5 and 99 nanometers (col. 6, lines 44+), this ratio encompasses all ratios recited in claims 1-4. Ranney also discloses that iron oxide-dextran complex) achieves increased intramolecular paramagnetism (becomes superparamagnetic) and can be used in his invention (col. 11, lines 46+). Note that iron is a radio-opaque material. In addition, Ranney disclosed that the microspheres of his composition have cores (abstract)

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Ranney is deficient in disclosing the kinds of iron oxides, the different polymer structures and the volume percentage of the magnetically responsive material.

Garibaldi discloses Embolic compositions for treating vascular defects such as aneurysms include a mixture of a biocompatible polymer material, a biocompatible solvent, and preferably also an adhesive Embolic compositions for treating vascular defects such as aneurysms include a mixture of a biocompatible polymer material, a biocompatible solvent, and preferably also an adhesive. The compositions preferably further comprise magnetic particles for controlling the delivery of the embolic agent. These magnetic particles preferably lose magnet strength over time, so that they do not interfere with subsequent magnetic diagnostic and therapeutic procedures. The compositions preferably also include radiopaque particles, which may be the magnetic particles, to facilitate imaging the embolic material (abstract). In the composition iron is used for both radiopacity and magnetic attraction (col. 4, lines 23+). Garibaldi included 40 weight percent magnetite (claim 16) and/or hematite (col. 12, lines 17+).

Garibaldi disclosed the use of long chain polymers. However neither Ranney nor Garibaldi disclosed the polymer backbone with the long chains of poly(propylene glycol) recited in the instant claims.

Unger teaches Improved methods for providing an image of an internal region of a patient. The composition disclosed by Unger includes a backbone polymer which is attached to a long chain polymer comprising polypropylene glycol (page 73 and page 39 respectively). Unger's compositions are used in MRI (page 70) and as a diagnostic or therapeutic (embolic) agent (page 45).

It would have been obvious to one skilled in the art to use hematite or magnetite since both iron oxides are known in the art to have magnetic properties needed to control the embolic material inside the vessel.

Accordingly, it would have been obvious for one skilled in the art at the time the invention was made to combine the disclosure of Ranney with the knowledge of Garibaldi because Garibaldi disclosed that his invention provides improved methods and related devices for treating vascular defects, and it would also be beneficial to adjoin Unger since his invention includes different versions and multiple techniques for a therapeutic embolic agent beside the diagnostic techniques.

Response to Arguments

3. Applicant's arguments filed 10/4/06 have been fully considered but they are not persuasive. Applicant argues that:

a. Contrary to Ranney, claim 1 teaches an outer layer that is hydrophobic. The presently claimed hydrophobic polymer coating feature allows the embolic material to retain the interfacial tension required to keep the magnetically responsive particles together when pulled by a magnetic gradient, which hydrophobic polymer portion may then be cleaved or degraded to yield a hydrophilically-coated magnetic particle which may then be removed by renal excretion, for example. (See paragraph 0052 of the presently published patent application 20040157082).

Ranney specifically teaches that the preferred polymer coating for the paramagnetic particles are hydrophilic, which is required to provide the

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necessary environment for reliable NMR results. Accordingly, Ranney specifically teaches away from the use of hydrophobic polymer coatings as in presently amended claims 1 and 36. Thus, Ranney does not teach or suggest an embolic material comprising a plurality of magnetically responsive particles having a non-magnetically responsive layer around the core, an outside portion of which includes hydrophobic polymer chains.

To respond to these arguments:

It is noted that Ranney does not teach an embolic composition (note that the “embolic composition” is recited in the preamble of the claim and does not have a patentable weight), accordingly, the reference teaches a soluble (hydrophilic outer coating). However, Garibaldi discloses an embolic composition, for that reason, the outer precipitating polymer (insoluble) at the site where the vascular defect is present.

b. Applicant argues that:

Garibaldi does not teach or suggest an embolic material comprising a plurality of magnetically responsive particles having a non-magnetically responsive layer around the core, an outside portion of which includes hydrophobic polymer chains. As such, the Applicant submits that claims 1 and 36 as presently amended are distinguished from Ranney and Garibaldi, and are allowable for at least these reasons.

To respond:

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Garibaldi is introduced to the rejection to because Ranney is deficient in disclosing the types of iron oxides recited in the instant application, however, Garibaldi discloses an embolic composition to treat vascular defects and discloses a particle coating that comprises a hydrophobic polymer (col. 3, lines 58+).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim
12/3/06



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER